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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,419	03/15/2004	John Lezdey	1434-19	1964

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JOHN LEZDEY & ASSOCIATES
2401 West Bay Drive
Suite 118
Largo, FL 33770

EXAMINER
BETTON, TIMOTHY E

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
03/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/801,419	LEZDEY ET AL.	
	Examiner	Art Unit	
	TIMOTHY E. BETTON	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,6 and 11-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4,6 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Remarks filed 3 December 2007 have been considered and duly made of record.

The essence of applicant's argument is directed to the alleged deficiency in the Lezdey, Perricone, Henley, and Weiner et al. references. Further, applicant maintains that one of ordinary skill in the art would not be so inclined as to combine the references together in such a way as to arrive at inventive objective of claimed invention.

Applicant's arguments have been thoroughly considered but are not found persuasive.

The fact remains in the art that cromolyn sodium is indicated for the prevention of the degranulation of mast cells and the control of the activation of PAR-2. Likewise, it is also well-known in the art that cyclodextrin is a penetrating agent used to enhance the penetration through the skin barrier at the first signs of inflammation.

Applicant asserts that the references as disclosed in the previous action *do* adequately address the inventive objective and subject matter embodied within the present invention.

Applicant further purports that the Office is employing hindsight using the present invention as a template in reference with cited references which fail to allegedly disclose embodiments drawn to the treatment of diaper rash or decubitus ulcers.

Lezdey et al. essentially teach cromolyn compounds which are generally indicated as a mast cell degranulation inhibitor. This in turn controls the release of chymase and tryptase which contribute to scarring. Perricone specifically teach inflammation and diaper rash dermatitis in addition to other types of skin inflammation. The disclosure of Perricone is broad and would reasonably find motivation via the teachings of Lezdey. Applicant, in the case of the Henley et

al. reference makes mention of a method of further enhancing the permeability of an agent via electrokinetic ultrasonic vibration applied to the dermis. This disclosure is merely incidental to the essential subject matter which does specifically teach the administration of cromolyn sodium comprised in a formulation for diaper rash. Weiner provides further motivation to incorporate the references together via the teaching that cyclodextrin is specifically indicated as permeability facilitating agent for a specific bioactive agent. In view of the above, it would be reasonably apparent to the skilled artisan that the methods and teachings of the references disclosed *supra* would be prima facie obvious in light of the claimed invention.

For the reasons already made of record, the 103(a) rejection is maintained.

Claim Rejections- 35 USC§103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2,4,6, and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey et al. (PGPUB US 2001/0041684 A1), Henley et al. (6,477,410 B1) and Perricone (USPN 6437004) in view of Weiner et al (USPN 5,834,014) and Gray, J., P&G Hair Care Research (P&G, hereinafter), [online], retrieved on 11/16/2007 (2003), retrieved from: http://www.pg.com/science/haircare/hair_twh_7.htm, printed pages 1 and 2).

Lezdey et al. teach a composition for healing burns and wounds in mammals, which contains a cromolyn compound or the combination of a cromolyn compound and hyaluronic acid a corticosteroid.

Lezdey et al. teach cromolyn compounds are inhibitors of PAR-2 and prevent the degranulation of mast cells so as to control the release of chymase and tryptase that may cause scarring (paragraph 15).

A preferred topical composition for use in serious injuries such as burns comprises by weight of the mixture: 0.01% to 1.50% calcium; 0.01% to 0.10% phosphate; 0.01% to 2.00% uric acid, 0.01% to 2.00% urea; 0.02% to 1.50% sodium; 0.01% to 0.10% potassium; 0.01% to 0.70% chloride; 0.001% to 0.01% magnesium; 0.01% to 2.50% hyaluronic acid; and 1.0% to 5.00% of a cromolyn compound (paragraph 16).

Otherwise, an occlusive bandage type of carrier such as vasoline or aquaphor can be used (paragraph 32).

Accordingly, Perricone teach free radical-scavenging olive oil polyphenols are topically applied to treat skin damage, such as contact dermatitis (particularly diaper area dermatitis), atopic dermatitis, xerosis, eczema (including severe hand and foot eczema), rosacea, seborrhea, psoriasis, thermal and radiation burns, other types of skin inflammation, and aging. Typical compositions contain from about 0.25% to about 10% of a polyphenol preparation obtained from olive oil (abstract, column 1, and lines 16-17, 23).

Lezdey et al. and Perricone do not teach a practicing administration of cromolyn compounds indicated for diaper rash or decubitus ulcers.

However, Henley et al teach a representative medicament of cromolyn sodium (column 3, line 19).

Henley et al. teach the treatment for fungal infestations of the skin comprising diaper rash (column 28, line 41).

Henley et al. teach a combination of an electrokinetically delivered substance into a tissue, together with inducing an ultrasonic vibration in the tissue, enables an opening of pores further facilitating penetration of the medicament (column 18, lines 20-27).

Henley et al. does not teach a practicing penetrating agent, i.e., cyclodextrin.

However, Weiner et al. teach cyclodextrin administered with a minoxidil derivative in order to facilitate permeability of said minoxidil agent into the scalp of the patient in need of such treatment (column 5, lines 23 and 38). In view of the disclosure of Weiner et al., Examiner directs applicant's attention to the disclosure from P&G Hair Care Research Center. The P&G reference teaches fine and soft hairs, which grow all over the baby's body. This is hair that develops on an unborn baby. It begins to grow about three months after the baby's conception (pg 1). Thus, the Weiner reference above holds merit in the case of cyclodextrin as indicated for diaper rash for facilitated permeability for the cromolyn sodium.

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of invention to at once recognize the reasonable expectation of success via the incorporating and the combining together of the inventions of Lezdey, Henley, and Weiner et al.

Lezdey et al. discloses the practicing administration of cromolyn compounds administered topically for variable skin irritations and disorders. Likewise, Henley et al. teach cromolyn sodium and a delivery system, which facilitates skin permeability via electrokinetics.

The methods and associated apparatus are different from the those disclosed in instant invention, however, the concept remains constant, in that, there is the element of the facilitation of skin permeability to increase efficacy of a topically applied medicament. Thus, Henley et al. supports the initial motivation to combine with the practicing administration of Lezdey et al. Accordingly, further motivation to combine together is taught in Weiner et al. Weiner et al. describes the penetrating agent, cyclodextrin as being well-known in the art as a facilitator of active agents/medicaments into the stratum corneum of the epidermis. Cyclodextrin is an agent, which could be interchanged with the electronic device of Henley et al. given in conjunction with the practicing medicament cromolyn sodium. Thus, the instant claims are made obvious over the teachings, methods, compositions, and techniques of Lezdey, Henley, and Weiner et al.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/

Primary Examiner, Art Unit 1617

TEB